IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 06-113-JJF
	:	(CONSOLIDATED)
	:	
DEY, L.P. and DEY, INC.,	:	
	:	
Defendant.	:	
	:	

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MEMORANDUM OPINION

September 24, 2009
Wilmington, Delaware

Farnan, District Judge.

Pending before the Court are Dey, L.P. and Dey, Inc.'s Motion For Summary Judgment Of Invalidity (D.I. 364) and Plaintiff Sepracor Inc.'s Motion For Summary Judgment Of No Anticipation Under 35 U.S.C. § 102 (D.I. 361). For the reasons discussed, the Court will grant-in-part Dey's Motion. Specifically, the Court concludes that there is no genuine issue of material fact that a reduction in side effects would be inherent in the use of R(-) albuterol for the treatment of asthma in humans. The Court will otherwise deny Dey's Motion. Also, for the reasons discussed, the Court will deny Sepracor's Motion.

I. BACKGROUND

A. Procedural Background

This patent infringement action is brought by Sepracor, Inc. ("Sepracor") against Dey, L.P and Dey, Inc. (collectively, "Dey"), alleging infringement of United States Patent Nos. 5,362,755 ("the '755 patent"); 5,547,994 ("the '994 patent"); 5,760,090 ("the '090 patent"); 5,844,002 ("the '002 patent") and 6,083,993 ("the '993 patent") (collectively the "patents-in-suit"), which pertain to methods of using the optically pure R(-) isomer of albuterol to treat bronchial disorders while at the same time reducing side effects associated with the use of the racemic mixture of albuterol.

The parties briefed their respective positions on claim construction, and, on July 18, 2008, the Court conducted a

Markman hearing on the disputed terms. On December 18, 2008, the Court issued a Memorandum Opinion construing the disputed terms. (See D.I. 311.) In accordance with the Court's Scheduling Order (D.I. 327) and the parties' stipulated modifications thereto (D.I. 360), on June 12, 2009, the parties filed the instant Motions.

B. Factual Background

The patents-in-suit pertain to methods of using the optically pure R(-) isomer of albuterol to treat bronchial disorders while at the same time reducing side effects that are allegedly associated with the use of the racemic mixture of albuterol. In general, the point of novelty of the patents-in-suit appears to be the claim that undesirable side effects associated with the use of racemic albuterol are attributable to either the S(+) enantioner of albuterol or the racemic mixture, but not the R(-) enantiomer by itself, which is generally thought to be responsible for the therapeutic effect of albuterol. Whether the R(-) enantiomer is, in fact, guiltless when it comes to albuterol's side effects remains a subject of dispute not only in the instant litigation but in the pharmaceutical community generally.

Sepracor asserts against Dey claims 1-3 of the '755 patent, claims 1-3 of the '994 patent, claims 1-4 of the '090 patent, claims 1-4 and 10 of the '002 patent, and claims 1-4 and 10-13 of

the '993 patent. A representative claim from the '755 patent is as follows:

> 1. A method of treating asthma in an individual with albuterol, while reducing side effects associated with chronic administration of racemic albuterol, comprising chronically administering to the individual a quantity of an optically pure R(-) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects, said R isomer being substantially free of its S(+) isomer.

Claim limitations of particular importance to the instant Motion are those that require, for instance, the administration of the "optically pure R(-) isomer of albuterol," a term that the patents-in-suit define to mean "a composition that contains at least 90% by weight of the R(-) isomer of albuterol and 10% by weight or less of the S(+) isomer." See, e.g., '755 patent at 2:20-24. All of the asserted claims include either this particular limitation or a limitation that explicitly requires the fraction of R(-) enantiomer to exceed a particular percentage. In no instance do the claims specify this particular percentage to be less than approximately 90% by weight.

Dey contends that Great Britain Patent Specification 1,298,494 ("GB '494"), which was published in 1972, anticipates the claims of the patents-in-suit. GB '494 "is concerned with a process for the preparation of optical enantiomers of certain 1-phenyl-2-aminoethanol derivatives . . . ," of which albuterol is one. GB '494 at 1:9-11. In particular, GB '494 explains as follows:

> The phenylaminoethanol derivatives (I) may exist in two optically isomeric forms and according to the invention we have discovered a new process for the preparation of such isomers; the advantage of this process is that it facilitates the production of pure isomers. This is of particular importance in this case since the pharmacological activity of one isomer in standard tests for bronchodilator action is very much greater than that of the other.

Id. at 1:24-33. Indeed, GB '494 discloses that "[t]he R(-) isomer . . . has been found to be approximately fifty times more active than the S(+) isomer in antagonising the increased bronchial resistance produced by administration of acetyl chlorine in the anaesthetized guinea-pig . . . ." Id. at 1:68-73.

With further regard to the "practical utility" of phenylaminoethanol derivatives, GB '494 explains that this topic "is more fully described in [Great Britain Patent Specification 1,200,886]." Id. at 1:20-22. Great Britain Patent Specification 1,200,886 ("GB '886"), in turn, explains, for example, that albuterol "has been tested on asthmatic patients and it was found that 100 μg., doses of this compound given by aerosol, are at least equal in speed of onset and intensity of action to isoprenaline at the same dose, and it is longer acting than isoprenaline." GB '886 at 2:13-15. Likewise, GB '886 states that "[t]he compounds according to the invention may be formulated for use in human or veterinary medicine for therapeutic or prophylactic purposes." Id. at 4:45-46.

II. DISCUSSION

A. Applicable Legal Principles

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there are triable issues of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. However, a court should not make credibility determinations or weigh the evidence.

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts. In the language of the Rule, the non-moving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" However, the mere existence of some evidence in support of the nonmovant will not be sufficient to support a denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the nonmovant on that issue. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

Pursuant to 35 U.S.C. § 102(b), a patent is invalid as anticipated if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." To anticipate a patent, a prior printed publication must contain each and every limitation of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the claimed invention without undue experimentation. Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000).

B. Dey's Motion For Summary Judgment Of Invalidity

1. The Parties' Contentions

Dey moves for summary judgment that GB '494 anticipates all claims of the patents-in-suit. The key aspects of Dey's anticipation argument may be summarized as follows. With regard to claim limitations that refer to the optical purity of the albuterol isomer (e.g., "optically pure R(-) isomer" or R(-) isomer content "greater than 99% by weight"), Dey contends that GB '494 discloses a method for resolving racemic albuterol into R(-) albuterol and S(+) albuterol such that at least 99% pure R(-) albuterol can be obtained. (D.I. 365 at 15.) To the extent GB '494 fails to explicitly disclose an exact percentage by weight of purity, Dey contends, first, that Dr. Roger Newton, a

scientist at the company that carried out the research that led to GB '494, testified that R(-) albuterol prepared according to the method in GB '494 would be as pure as 99%. Second, Dey contends that polarimetry experiments conducted by its expert witness, Dr. Daniel Armstrong, confirm that GB '494 did in fact disclose R(-) albuterol of greater than 99% purity.

As to the remaining claim limitations of the patents-in-suit, Dey relies mainly on the teachings of GB '886, which Dey contends is incorporated by reference into GB '494. Briefly, to the extent the claims of the patents-in-suit require the treatment of asthma or other bronchial disorders, Dey notes that GB '886 discloses inter alia that albuterol "has been tested on asthmatic patients" and "has been found to be an effective bronchodilator in human beings . . . ." GB '886 at 2:8-19. As to claim limitations that refer to the manner of asthma treatment (e.g., whether administration is "chronic" or "acute"), Dey notes that GB '886 discloses administration of albuterol to humans for "therapeutic and prophylactic purposes." GB '886 at 4:46-47. Finally, with regard to the requirement that side effects be reduced, Dey contends that this is inherently disclosed in GB '494 because, to the extent the administration of the R(-) isomer of albuterol actually leads to fewer side effects than the administration of racemic albuterol, this is merely the natural result of administering only the R(-) isomer of albuterol. See

Eli Lilly & Co. v. Barr Labs., 251 F.3d 955, 970 (Fed. Cir. 2001) ("A reference includes an inherent characteristic if that characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations.").

Sepracor has four responses to Dey's anticipation argument. First, Sepracor contends that genuine issues of fact exist as to precisely what GB '886 and GB '449 actually disclose. In particular, Sepracor contends that both of these references fail to disclose "(1) that there are side effects associated with racemic albuterol, (2) the use of optically pure R(-) albuterol to treat humans, or (3) that side effects associated with racemic albuterol in humans can be reduced by treating humans with optically pure R(-) albuterol." (D.I. 373 at 15.) Second, although incorporation by reference is a question of law,[1] Sepracor contends that there is an issue as to "whether these two unrelated patents can be stitched together for anticipation." (D.I. 373 at 12.) Specifically, Sepracor maintains that "it is plain that GB '494 only references GB '886 as background, related prior art." (Id. at 16.) Sepracor further points to the declaration of the inventor of GB '494, Dr. David Middlemiss, who states that "it is not possible that GB '886 is part of my

[1] See Advanced Display Sys. v. Kent State Univ., 212 F.3d 1272, 1283 (Fed. Cir. 2000) ("Whether and to what extent material has been incorporated by reference into a host document is a question of law.").

invention because I have never read the GB '886 patent." (D.I. 375 ¶ 16.) Sepracor thus argues that "if the sole inventor has never read GB '886, it logically cannot be part of his invention disclosure." (D.I. 373 at 17.) Third, Sepracor contends that there are genuine issues of fact as to whether GB '494 discloses optically pure R(-) albuterol. According to Sepracor, the polarimetry tests of Dey's expert, Dr. Armstrong, are (1) unreliable, and (2) not even capable of establishing whether a sample is greater than 99% purity. Finally, Sepracor contends that Dey has conceded that GB '494 does not inherently anticipate the claimed reduction in side effects. Briefly, Sepracor notes that Dey's expert asserts that "there is still no convincing evidence today that clinical use of the optically pure R(-) isomer of albuterol rather that [sic] racemic albuterol will reduce adverse effects." (D.I. 374, Exh. 12 ¶ 30.) Sepracor maintains that this position undermines Dey's inherent anticipation defense because "[i]f a reduction in side effecets never occurs with the administration of optically pure R(-) albuterol, as Dey asserts, then under no circumstances can GB '494 and GB '886, whether taken alone or together, be argued to disclose expressly or inherently Sepracor's claimed reduction in side effects." (D.I. 373 at 26-27.)

2. Decision

In the Court's view, summary judgment is not appropriate because a genuine issue of material fact remains as to whether GB '494 discloses R(-) albuterol having a level of purity within the scope of the claims of the patents-in-suit. Dey relies on two main pieces of evidence in support of its position that GB '494 discloses at least 99% pure R(-) albuterol. First, Dey points to the deposition testimony of Dr. Roger Newton, who is a medicinal chemist and former Chair of the Respiratory Research Management Committee for Allen & Hanburys, the British company that conducted the research that led to GB '494. With regard to the level of purity that could be obtained using the methods disclosed in GB '494, Dey points out that Dr. Newton testified, inter alia, that "it wouldn't have surprised me if it was somewhere around 98.5, 99 percent pure." (D.I. 365 at 15 (quoting D.I. 366, Exh. 16 at 220:22-222;5.)) However, Dey also notes that Dr. Newton testified that "I cannot tell you what they achieved because I wasn't there." (Id.) Likewise, Sepracor points out that Dr. Newton testified as follows:

> Q. And what level of optical purity is the compounds in GB494?
>
> A. Well, I've just explained that. You don't know because there was no way in the time in which this was done that you can tell.

(D.I. 374, Exh. 11 at 208:13-20 (objection omitted).) Dr. Newton also testified as follows:

> Q. So is it your testimony that in GB494, you can't tell whether or not the R isomer of albuterol is 90 percent pure or 99 percent pure?
>
> A. You can't tell, but because they have gone to constant melting point and constant rotation, that's called specific rotation, you would expect it to be better than 90 percent.
>
> You would expect it to be better than 95 percent, but whether it is 97.5 or 92.5 or 98.5, no, there isn't a way of telling. But the skilled person would accept that this is technically as pure in those days you could make it.

(Id. at 216:2-13.) After reviewing Dr. Newton's testimony, the Court concludes that Dr. Newton is inconclusive as to the exact level of purity disclosed in GB '494. In these circumstances, Dr. Newton's testimony does not support summary judgment.

The second main piece of evidence Dey points to in support of its Motion For Summary Judgment are the polarimetry experiments of its expert witness, Dr. Armstrong. Briefly, Dr. Armstrong measured the optical rotation produced by a sample of commercially obtained optically pure R(-) albuterol (i.e., greater than 99% purity) and obtained results within experimental error of the optical rotation values reported in GB '494. (See D.I. 368, Exh. 17 ¶ 18.) Based on this, Dr. Armstrong concludes that "because the specific rotation of the pure samples was identical within the experimental error of the method, i.e. -36.8° vs. -36.9° and -37.3° vs. -36.9°, the product synthesized in the publication was >99% pure." (Id.)

As an initial matter, the Court agrees with Sepracor that there is no reason to believe that the material tested by Dr. Armstrong was prepared by the process set forth in GB '494. Accordingly, there remains a genuine issue of fact as to whether the material Dr. Armstrong tested is, in fact, the same as what GB '494 describes. Furthermore, Dr. Armstrong testified in his deposition as follows:

> Q. Now, when you gave your opinions as to 95 percent or 99 percent, is there some statistical analysis that you did to determine that?
>
> A. If you look at the error, the polarimetry measurements, the plus or minus a certain amount and you assume you get the maximum error, than you would - you would get the same number essentially for polarimetry if you had 95 percent or 100 percent because of the lack of precision, the precision of the method gives you that amount of error.
>
> And it's generally accepted that polarimetry at low levels gives you a significant error like that because of the precision of the method, which is why we've gone to HPLC methods.

(D.I. 374, Exh. 9, 76:7-23.) Dr. Armstrong further testified that his own polarimetry experiments had an error somewhere between 9 and 10%. (Id. at 72:7-19.) On reviewing Dey's Reply Brief in support of its Motion For Summary Judgment, the Court concludes that although Dey emphasizes Dr. Armstrong's overall conclusion that GB '494 discloses 99% pure R(-) albuterol, Dey does not adequately refute this testimony. Along these lines, Sepracor's expert witness, Dr. Henry I. Mosberg, testified that polarimetry is "not particularly precise," "not extremely

informative," and that it has "inherent error." (D.I. 374, Exh. 10 at 21:7-25.) Specifically, Dr. Mosberg testified that at the relevant concentrations an error of 10 percent was inherent in the polarimetry method. (Id. 187:23-188:3.) Given the conflicting expert testimony and the questions surrounding the accuracy of Dr. Armstrong's polarimetry experiments, the Court concludes that a genuine issue of material fact remains as to whether GB '494 genuinely discloses R(-) albuterol of a purity within the scope of the claims, which precludes summary judgment on the overall issue of anticipation.

Although the Court concludes that summary judgment on the overall issue of anticipation is inappropriate, the Court concludes that summary judgment on the issue of whether a reduction in side effects is inherent in the use of R(-) albuterol is warranted. Put another way, to the extent Dey is able to establish at trial that the prior art discloses the use of R(-) albuterol for the treatment of asthma in humans, the Court concludes that there is no genuine issue of material fact that a reduction in side effects would be inherent in such use.[2]

Instructive here is the Federal Circuit's decision in In re Cruciferous Sprout Litig., 301 F.3d 1343, 1350 (Fed. Cir. 2002).

[2] The Court acknowledges that the parties continue to dispute whether the administration of R(-) albuterol actually leads to a reduction in side effects relative to the administration of racemic albuterol. To be clear, the Court is not, at this time, making a factual finding on this issue.

There, the patentee claimed "A method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." In re Cruciferous Sprout, 301 F.3d at 1345. The patentee did "not claim to have invented a new kind of sprout, or a new way of growing or harvesting sprouts," but merely "recognized that some sprouts are rich in glucosinolates," which have a chemoprotective effect against cancer. Id. at 1345, 1350. In holding that the patent was anticipated, the Federal Circuit explained that the patentee "has done nothing more than recognize properties inherent in certain prior art sprouts" and that while the patentee "may have recognized something quite interesting about those sprouts, it simply has not invented anything new." Id. at 1350-51. In the Court's view, to the extent the prior art discloses the use of R(-) albuterol for the treatment of asthma in humans, this case would be indistinguishable from In re Cruciferous Sprout. Indeed, similar to In re Cruciferous Sprout, the recognition that R(-) albuterol causes fewer side effects as compared to racemic albuterol would not be a new invention, but merely the recognition of something interesting about R(-) albuterol. Accordingly, the Court will grant in part Dey's Motion For Summary Judgment. On the overall issue of anticipation, the

Court will deny Dey's Motion. However, following In re Cruciferous Sprout, the Court further concludes that to the extent Dey establishes that the prior art discloses the use of optically pure R(-) albuterol for the treatment of asthma in humans, the claimed reduction in side effects would be inherent in such art.[3]

Sepracor appears to argue that some portion of patients simply do not experience side effects when administered albuterol, and, as a result, that the "administration of optically pure R(-) albuterol will not 'necessarily and inevitably' result in a reduction of side effects," which is required for inherent anticipation. See Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002) ("Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art.") (quoting In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999)). In support of this position, Sepracor relies heavily on Glaxo Group Ltd. v. Teva Pharms. United States, No. 02-219-GMS, 2004 U.S. Dist. LEXIS 16750, at *54 (D. Del. Aug. 20, 2004). However, the Glaxo case "invoke[d] the distinction between a new use and an added benefit." Id. at *54. The former, which was at issue in Glaxo, may be the subject of a

[3] The Court reserves decision on the issue of whether and to what extent GB '494 incorporates by references GB '886.

valid patent, but the latter may not. Id. Here, unlike Glaxo, to the extent the prior art discloses the use of R(-) albuterol for the treatment of asthma in humans, the claims would be directed not to a new use, but merely an added benefit of an old use. Accordingly, Glaxo is not on point.

More importantly, Sepracor's argument that there can be no inherent anticipation simply because not all patients actually suffer side effects when administered racemic albuterol is unpersuasive. If, as Sepracor plainly contends, such side effects - to the extent present - may be reduced through the use of optically pure R(-) albuterol, it is of no moment that some patients are fortunate enough to not be susceptible to such side effects in the first place. The claimed reduction in side effects - to the extent they exist - would still be necessarily and inevitably present in the use of optically pure R(-) albuterol. Cf. Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349 (Fed. Cir. 1999) (finding inherent anticipation where a prior art reference disclosed a range of compositions in which some, but not all, of the disclosed compositions exhibited the claimed "entrapped" aeration).

Finally, the Court is unpersuaded by Sepracor's argument that Dey is estopped from arguing anticipation because Dey's expert witness remains unconvinced that the use of optically pure R(-) albuterol actually reduces adverse side effects relative to

racemic albuterol. Indeed, Sepracor's patent claims explicitly require a reduction in side effects, and Sepracor argues that "[t]he evidence at trial will show that when Dey's levalbuterol product is administered to the relevant patient population, some significant portion of those patients will experience a reduction of side effects relative to a patient population taking racemic albuterol." (D.I. 373 at 27 n.10.) Nevertheless, for the purpose of deciding in its favor on anticipation, Sepracor asks the Court to credit the opinion of Dey's expert that the use of R(-) albuterol does not actually reduce side effects. However, for the purpose of finding in Sepracor's favor on the issue of infringement, Sepracor will undoubtedly ask the Court to reject this opinion. The Court cannot accept such shifting arguments.

Dey, on the other hand, presents the Court with alternative arguments. Dey contends, first, that there is not actually a reduction in side effects attributable to the use of optically pure R(-) albuterol, in which case it may not infringe. Alternatively, to the extent the Court concludes that the administration of optically pure R(-) albuterol does reduce side effects relative to racemic albuterol, Dey contends that GB '494 anticipates the patents-in-suit. But Dey does not invite the Court to adopt these inconsistent positions at different

stages in the litigation. Rather, Dey asks only that the Court, in the end, follow a consistent path.

C. Plaintiff Sepracor Inc.'s Motion For Summary Judgment of No Anticipation Under 35 U.S.C. § 102

In its Motion For Summary Judgment, Sepracor offers two reasons why GB '494 does not anticipate the claims of the patents-in-suit. First, Sepracor contends that neither GB '494 nor GB '886 disclose "(1) that there are side effects associated with racemic albuterol, (2) the use of optically pure R(-) albuterol to treat humans, or (3) that side effects associated with racemic albuterol can be reduced by treating humans with optically pure R(-) albuterol." (D.I. 362 at 10-11.) Points (1) and (3) focus mainly on the issue of inherent anticipation, which the Court has addressed above in connection with its discussion of Dey's Motion For Summary Judgment. As to point (2) – whether GB '494 specifically discloses "the use of optically pure R(-) albuterol to treat humans" – the Court notes that GB '494 discloses that resolving racemic phenylaminoethanol derivatives into its enantiomers is of "particular importance" because "the pharmacological activity of one isomer in standard tests for bronchodilator action is very much greater than that of the other." GB '494 at 1:23-33. In light of this disclosure, the Court concludes that summary judgment is not warranted on the issue of whether GB '494 discloses the use of optically pure R(-) albuterol to treat humans.

Second, Sepracor contends that "Dey's own admissions and arguments preclude a finding of inherent anticipation." (Id. at 17.) Specifically, Sepracor notes that Dey and its expert witnesses argue that the use of optically pure R(-) albuterol does not necessarily lead to a reduction in side effects. Though insisting that the administration of pure R(-) albuterol reduces side effects in a significant portion of patients, (see D.I. 373 at 27 n.10), Sepracor contends that "if as Dey argues, the claimed result of Sepracor's claims never happens, then Dey cannot argue that this result is taught or inherently disclosed by GB '494 and GB '886." (D.I. 362 at 19.) The Court has addressed this argument in connection with its discussion of Dey's Motion For Summary Judgment. Briefly, the Court concludes that Dey's arguments regarding whether optically pure R(-) albuterol actually produces fewer adverse side effects relative to racemic albuterol do not preclude it from arguing anticipation by GB '494.

Accordingly, the Court will deny Sepracor's Motion For Summary Judgment.

III. CONCLUSION

For the reasons discussed, the Court will grant-in-part Dey's Motion For Summary Judgment Of Invalidity (D.I. 364) and deny Plaintiff Sepracor Inc.'s Motion For Summary Judgment Of No Anticipation Under 35 U.S.C. § 102 (D.I. 361).